K061667

JUL 10 2006

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act 1990 and 21 CFR 807.92.
	CELL-DYN Ruby™ System
Submitted by:	Abbott Laboratories 5440 Patrick Henry Drive Santa Clara, CA 95054
Contact Person:	Michelle Roeding Phone: (408) 567-3781 Fax: (408) 982-4863
Date Prepared:	June 13, 2006
Proprietary Name	CELL-DYN Ruby™ System
Common Name:	Automated Hematology Analyzer
Classification Name:	Automated Differential Cell Counter (21 CRF 864.5220)
Predicate Device:	CELL-DYN® 3200 System K972354 – September 16, 1997 K980614 – April 24, 1998 K012934 – September 28, 2001
Intended Use:	The CELL-DYN Ruby System is a multiparameter, automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories and physician office laboratories.
Device Description:	The CELL-DYN Ruby System is a tabletop analyzer consisting of the main analyzer, data module, flat panel display station, and printer. The main analyzer and data module are housed in a single chassis. The display station and printer are stand-alone modules. The CELL-DYN Ruby is equipped with a Sample Loader that provides continuous automated closed sampling for up to 50 closed tube samples at a time. The instrument's utilizes the CELL-DYN MAPSS™ technology, laser flow cytometry and a Microsoft® Windows® Operating System, USB connectivity on the data module to allow the interface of a wide variety of printer types and a standard

hand-held bar code reader to help expedite patient specimen identification.

Similarities and Differences:

The CELL-DYN 3200 and the CELL-DYN Ruby System are similar in that:

a. Both systems consist of an Analyzer and Data Module housed in a single chassis with a standalone display.

b. Both systems provide quantitation of the hemogram and automated WBC differential parameters in EDTA-anticoagulated human whole blood specimens.

c. Both systems will accept specimens presented automatically by the autoloader or manually presented by the operator.

d. Both systems utilize laser optical scatter (WBC, RBC and PLT) and optical absorbance methods (HGB) using a Helium Neon laser.

e. Both systems utilize a single step offline staining procedure for reticulocyte analysis.

f. Both systems provide Dispersional Data Alerts, Suspect Parameter Messages, and Suspect Population Flags to assist in data review.

g. Both systems accept input from the keyboard and send data output to: video screen, hard drive, and printer; and both systems provide RS232 Interface to an on-line LIS as well as using microprocessors for systems control, data acquisition, and data analysis.

h. Both systems utilize the same reagent formulations.

i. Both systems have Moving Average Programs (X-B) for WBC, RBC parameters and the capability to download QC to media for online peer QC review.

j. Both systems are able to search patient demographics.

The CELL-DYN Ruby System and the CELL-DYN 3200 System are different in that:

a. The CELL-DYN Ruby uses a Microsoft® Windows® XP operating system, while the CELL-DYN 3200 uses Microsoft® DOS operating system.

b. The CELL-DYN Ruby incorporates a mouse for software navigation, a 17 inch touch sensitive LCD display, and a hand held barcode reader for patient and control identification, where the CELL-DYN 3200 does not have any of these options.

c. The CELL-DYN Ruby has software wizards which step users through less routinely performed processes, while the CELL-DYN 3200 does not have this feature.

d. The CELL-DYN Ruby has a CD-ROM or DVD Drive that allows the installation of software, and online maintenance videos and online help manual, while the CELL-DYN 3200 uses a floppy disk drive to download and upload information and does not have the online help capability.

e. The CELL-DYN Ruby includes the ability to have interactions and remote instrument monitoring through AbbottLink, while the CELL-DYN 3200 only acts as a passive communicator and provides number of cycles performed on the analyzer.

f. The CELL-DYN Ruby uses an increased size configuration of WBC Lyse reagent when compared to the current CELL-DYN 3200 configuration.

g. The CELL-DYN Ruby Quality Control Moving Average programs (X-B) has been expanded to include PLT and RETC parameters and is capable of downloading reticulocytes QC to media for online peer QC Review, while the CELL-DYN 3200 does not have the same QC capability for Reticulocytes.

h. The CELL-DYN Ruby is able to search and filter the datalog and system log, while the CELL-DYN 3200 only searches patient demographics and does not have a system log.

i. The CELL-DYN Ruby incorporates WOC and HGB reagent heaters to bring the reagents within a required temperature range while the CELL-DYN 3200 does not.

Equivalency Data:

The analysis above supports the claim that the CELL-DYN Ruby System is substantially equivalent to the CELL-DYN 3200 System.

Data on file at Abbott Laboratories consisting of background, carryover, imprecision (reproducibility), analytical measurement range (linearity), and sensitivity and specificity information shows performance to the manufacturer's specifications.

Conclusion:

The CELL-DYN Ruby System demonstrates substantial equivalence to the predicate device.

Truthful and Accurate Certification

A certification of the truthfulness and accuracy of the CELL-DYN Ruby System described in this submission is provided in Attachment I.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Michelle Roeding
Section Manager, Regulatory Affairs
Abbott Laboratories
5440 Patrick Henry Drive
Santa Clara, California 95054

JUL 10 2006

Re: k061667
Trade/Device Name: CELL-DYN Ruby™ System
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential counter cell
Regulatory Class: II
Product Code: GKZ
Dated: June 13, 2006
Received: June 14, 2006

Dear Ms. Roeding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061667

Device Name: CELL-DYN Ruby™ System

Indications for Use:

The CELL-DYN Ruby System is designed to analyze EDTA-anticoagulated blood and report the following hematological parameters:

White Blood Cell Parameters	**Red Blood Cell Parameters**
WBC – White Blood Cell Concentration NEU – Neutrophil Absolute Concentration %N – Neutrophil Percentage of WBC LYM – Lymphocyte Absolute Concentration %L – Lymphocyte Percentage of WBC MONO – Monocyte Absolute Concentration %M – Monocyte Percentage of WBC EOS – Eosinophil Absolute Concentration %E – Eosinophil Percentage of WBC BASO – Basophil Absolute Concentration %B – Basophil Percentage of WBC **Platelet Parameters** PLT- Platelet Concentration MPV- Mean Platelet Volume	RBC – Red Blood Cell Concentration HCT - Hematocrit MCV – Mean Cell Volume RDW – Red Cell Distribution Width %R – Reticulocyte Percent RETC - Reticulocyte Absolute Concentration **Hemoglobin Parameters** HGB – Hemoglobin Concentration MCH – Mean Cell Hemoglobin MCHC – Mean Cell Hemoglobin Concentration

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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